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10/607,434	06/26/2003	Mark P. Anstadt	034448-007	5213

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EXAMINER
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OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3766

NOTIFICATION DATE	DELIVERY MODE
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08/11/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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## **DETAILED ACTION**

### ***Response***

1. The Applicant cancelled all the claims previously being prosecuted and entered new claims 245-255 in the response filed 4/29/08, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.
2. As suggested by the Applicant, it appears that in light of recasting the independent claims, it is appropriate that most of not all of the withdrawn claims be included in the prosecution, hence in reply to this action, it is suggested the Applicant amended the withdrawn claims 132, 134-149, 156, 157 and 159-162 to reflect dependence on the claims currently being prosecuted, claims 245-255. The Applicant is cautioned that the amendments must be consistent with the descriptions of the various embodiments in the application as originally filed.

### ***Claim Rejections - 35 USC § 103***

3. Claims 245-255 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsitlik et al. (U.S. Patent No. 5,971,910) in view of Kung et al. (U.S. Patent No. 6,626,821).

Tsitlik et al. disclose a method and deformable apparatus for treating a patient requiring heart function assistance or therapy, the invention comprising a compliant cup having an external wall (14) attached to a liner (22) forming a continuous annular cavity (36) between the wall and the liner, the cavity holding a varying volume of pressurized fluid, a heart receiving chamber (34), and a drive system (not shown) accepted to have an algorithm (column 3, lines 30-51;

column 4, line 47 – column 5, line 15; column 5, lines 44-50, 65-67; column 10, lines 44-49; column 11, lines 22-24).

As discussed in the previous paragraph of this action, Tsitlik et al. disclose the claimed invention except:

1) the cardiac assist device using the algorithm in the control system to effect fluid displacement in the annular cavity between the wall and liner, the cavity configured as a single continuous cavity or configured as an annular cavity having two chambers, the fluid displacement based on hemodynamic data, fluid pressure, enabling the assessment of the device during installation and enabling the maintenance of constant cardiac performance during treatment (claims 245-248, 251, 253-255), and

2) multiple sensors, the sensors being remote to the cup (claim 249), the sensors being electrodes positioned externally on the patient to provide electrophysiological data (claim 250), and the sensors to confirm consistent liner contact with the external surface of the heart (claim 252).

As to the control system, Kung et al. disclose flow balancing in a cardiac assist device using an algorithm to effect fluid displacement in the annular cavity, the cavity configured as a single continuous cavity and configured as an annular cavity having two chambers, the fluid displacement based on the hemodynamic data, fluid pressure, for the purpose of enabling the assessment of the device during installation and enabling the maintenance of constant cardiac performance during treatment. It would have been obvious to one having ordinary skill in the art at the time of the invention to have an algorithm based control system to effect displacement in between the wall and liner, the cavity configured as a single continuous cavity and configured as

an annular cavity having two chambers, the displacement based on hemodynamic data, fluid pressure, in the Tsitlik et al. system in order to provide active assistance to the pumping action of the ventricles using patient customized control parameters, the volume of the inflation fluid at specific flow rates, enabling the attainment of the desired cardiac pumping characteristics (abstract; column 3, lines 52-61; column 6, lines 2-19, 49-54; column 12, lines 40-67).

As to sensors, Kung et al. disclose flow balancing in a ventricular assist device using multiple sensors including sensors remote from the cup, specifically electrodes positioned externally on the patient to provide electrophysiological data (such as external pacemaker data), and sensors to confirm consistent liner contact with the external surface of the heart (such as pressure sensors applied to the wrap) for the purpose of controlling the device based on patient specific data. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used multiple sensors, the sensors being remote to the cup, the sensors being electrodes positioned externally on the patient to provide electrophysiological data, and the sensors to confirm consistent liner contact with the external surface of the heart in the Tsitlik et al. system in order to provide active assistance to the pumping action of the ventricles using customized control parameters based on physiological data from the patient, enabling synchronization of the pump operation with the pumping action of each ventricle so the desired cardiac pumping characteristics are attained (abstract; column 3, lines 52-61; column 6, lines 2-19; column 13, lines 23-40).

***Statutory Basis***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. Fran's schedule typically is Monday and Tuesday 9AM-7PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. Carl's schedule typically is Monday, Wednesday, Friday 9AM-5 PM EST; Tuesday, Thursday 9AM-3PM and 9PM-11PM EST. The fax phone numbers for the

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organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

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/Frances P. Oropeza/

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